

# EXHIBIT 3

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

**IN RE: C.R. BARD, INC., PELVIC REPAIR  
SYSTEM PRODUCTS LIABILITY LITIGATION**

**MDL NO. 2187**

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**THIS DOCUMENT RELATES TO**

**PATRICIA BOLYARD**

**Plaintiff,**

**v.**

**Case No. 2:12-cv-126**

**C.R. BARD, INC.,**

**Defendant.**

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**RULE 26 EXPERT REPORT OF DANIEL S. ELLIOTT, M.D.**  
**FOR PATRICIA BOLYARD**

I am providing my expert opinion regarding the Plaintiff, Patricia Bolyard. The following represent my opinions, all held to a reasonable degree of medical probability and certainty. These opinions are based upon my background, training and experience as well as the totality of available data from all sources, which I have reviewed. I have served my General Causation Expert report in MDL 2187 concerning Avaulta Plus and Avaulta Solo products. I rely upon my General Causation Expert report and incorporate that document by reference. I reserve the right to supplement this report if new or supplemental information is provided at any point, and as I review other related documents.

**I. QUALIFICATIONS**

I am an Associate Professor of Urology, section of Female Urology and Reconstructive Surgery, at Mayo Clinic Graduate School of Medicine in Rochester, Minnesota. My current curriculum vita, attached hereto as Exhibit "A", more fully and accurately reflects my training, background, academic activity and publications. However, briefly, I received an M.D. in 1993 from Loma Linda University School of Medicine in Loma Linda, California. Following graduation from medical school, I completed one year of General Surgery and five years of Surgical Urology residency at the Mayo Graduate School of Medicine at the Mayo Clinic in 1999. I then completed a one-year advanced surgical fellowship at Baylor College of Medicine in Houston, Texas, in Neurourology, Urodynamics and Voiding Dysfunction. I then re-joined the faculty at the Mayo Clinic, where I have spent the last fourteen years specializing in treating pelvic organ prolapse and urinary incontinence in women and urinary incontinence in men. I have published nearly 60 peer-reviewed articles and given over a 100 lectures nationally and

internationally pertaining to urinary incontinence and pelvic organ prolapse. I have specifically authored two published scientific manuscripts dealing with polypropylene meshes in the animal model. A Mayo Clinic colleague and I were the first to perform robotic sacrocolpopexy surgery for the treatment of high-grade prolapse and to publish extensively on the subject and the first to perform and publish on the outpatient, non-mesh transobturator sling.

During my training, I was introduced to the use of synthetic midurethral slings for incontinence repair. I have used the Mentor OB/Tape products as well as mesh slings made by AMS and Coloplast. As of almost a year ago, I decided to no longer use meshes in my practice through the transvaginal route unless there is absolutely no other alternative. The reason that I made this decision is that my practice has become increasingly dedicated to treating a whole host of life-altering complications associated with the use of both SUI and POP meshes, including meshes made by Bard. Neither I, nor my colleagues at Mayo, have ever used transvaginal POP kits as we felt that the risk to patients was too great. Having treated hundreds of patients with mesh-related complications (both SUI and POP), I feel that we made the right decision not to include them as part of our treatment regimen. I only use mesh for POP repair through robotic sacrocolpopexy as it is not a transvaginal surgery, uses much less mesh, and is associated with significantly less complications than transvaginal mesh prolapse repair.

I am a frequent invited national and international lecturer at medical and surgical conferences addressing stress urinary incontinence and pelvic organ prolapse, their evaluation, treatment, surgical options and management of complications. I have taken and passed the subspecialty credentialing process recently established by the combined boards of the American Board of Urology and American Board of Obstetrics and Gynecology in Female Pelvic Medicine and Reconstructive Surgery.

I am attaching my Curriculum Vitae (Exhibit "A"). I am also attaching a copy of my testimony for the last four years (Exhibit "B"). My reliance documents are listed on Exhibit "C".

## **II. PATRICIA BOLYARD MEDICAL RECORDS REVIEW AND CASE REPORT**

At the time of her 2008 Avaulta placement, Ms. Bolyard was a 70 year old woman who had three vaginal deliveries. Ms. Bolyard initially presented to Dr. Tyler Prouty on April 14, 2010 with a chief complaint of bleeding, vaginal discomfort, and inability to have sex due to pain.<sup>1</sup>

Ms. Bolyard's surgical history consists of an abdominal hysterectomy, bilateral oophorectomy, total thyroidectomy, bilateral salpingectomy, tonsillectomy, and an appendectomy. Her medical history includes lymphoma, breast pain, vaginal irritation, bladder problems, chronic obstructive pulmonary disease, hypertension, diabetes, constipation, hypothyroid, and heart disease. Ms. Bolyard is also a former smoker.<sup>2</sup>

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<sup>1</sup>BOLYARDP\_WHWEC\_MDR00040-41

<sup>2</sup>Deposition of Patricia Bolyard at 91.

Prior to Ms. Bolyard surgery for pelvic organ prolapse on July 2, 2010, Ms. Bolyard complained of mild overactive bladder such as urinary urgency and urinary frequency.<sup>3</sup> She complained of symptoms consistent with pelvic organ prolapse such as pelvic fullness, pelvic pressure, sensation of “something falling out of the vagina” and vaginal irritation. She specifically denied symptoms consistent with pelvic pain, or pain with activity such as lifting or walking. Prior to her surgery Ms. Bolyard was sexually active, however, because of her diagnosis of lichen sclerosis she did describe pain with intercourse at the introitus with insertion.<sup>4</sup> On the visual analog scale, Ms. Bolyard gave this perineal pain with sexual activity a score of 7 (out of 10).

On July 2, 2010 Dr. Tyler Prouty performed pelvic organ prolapse surgery on Ms. Bolyard.<sup>5</sup> The surgery performed was to treat a grade 4 rectocele, grade 1 enterocele and a grade 2 cystocele and to treat perineal lichen sclerosis. Dr. Prouty performed an uncomplicated Anterior and Posterior Avaulta Solo mesh<sup>6</sup> implantation and an excision of perineal lichen sclerosus. Careful examination of the rectum at the end of the case demonstrated no rectal injury. Dr. Prouty specifically made sure to tension the mesh appropriately “No tension or bridging of any tissues or graft material.”<sup>7</sup> Dr. Prouty also made sure the vaginal epithelial flap was healthy and thick to reduce the risk of postoperative mesh exposure “Good full-thickness epithelium was placed over the graft and good full-thickness coverage of the graft was accomplished.”<sup>8</sup> During the immediate postoperative period Ms. Bolyard had no difficulty and was dismissed from the hospital on the second postoperative day.<sup>9</sup>

Beginning in the summer of 2011 Ms. Bolyard began complaining of progressively worsening pain with sexual activity, bloody vaginal discharge and burning vaginal pain. The pain and discomfort progressed to the point that she sought medical attention from Dr. Prouty on October 27, 2011.<sup>10</sup> Dr. Prouty recorded that Ms. Bolyard “Complains of entry & post coital dyspareunia-intense burning.”<sup>11</sup> Dr. Prouty performed a thorough exam on October 27, 2011 and noted “On speculum exam, 8 mm section of graft is visibly exposed.”<sup>12</sup> Dr. Prouty decided conservative treatment and observation was the most appropriate initial treatment. Ms. Bolyard returned to Dr. Prouty’s office on December 22, 2011 with persistent complaints of painful sexual activity. Dr. Prouty repeated his physical exam which demonstrated “on exam, graft is similar; watch & re[check].”<sup>13</sup>

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<sup>3</sup> BolyardP\_WHWEC\_MDR00037-41; BolyardP\_WCA\_MDR00002; Deposition of Patricia Bolyard at 205.

<sup>4</sup> BolyardP\_WCA\_MDR00002-4

<sup>5</sup> BolyardP\_FAGH\_MDR00242-243

<sup>6</sup> BolyardP\_FAGH\_MDR00250

<sup>7</sup> BolyardP\_WHWEC\_MDR00023-25

<sup>8</sup> BolyardP\_WHWEC\_MDR00024

<sup>9</sup> BolyardP\_FAGH\_MDR00022

<sup>10</sup> BolyardP\_WHWEC\_MDR00029-33

<sup>11</sup> BolyardP\_WHWEC\_MDR00031

<sup>12</sup> BolyardP\_WHWEC\_MDR00031

<sup>13</sup> BolyardP\_WHWEC\_MDR00027

Conservative therapy failed for Ms. Bolyard and her symptoms progressed to the point where she needed a repeat surgical intervention in an attempt to treat the mesh exposure and the dyspareunia. On February 8, 2012 Dr. Prouty returned Ms. Bolyard to the operating room and performed an excision of Avaulta mesh located on the anterior vaginal wall.<sup>14</sup> He also performed a cystoscopy, which showed no evidence of a bladder erosion.<sup>15</sup> The procedure was uncomplicated and Dr. Prouty resected all the visible mesh that was exposed. On the two-week postoperative visit Ms. Bolyard was doing well and had no complaints.<sup>16</sup>

However, by August 2013 Ms. Bolyard had returned to Dr. Prouty with recurrent and worsening dyspareunia, pelvic pain, vaginal pain, and vaginal mesh exposure. On exam Dr. Prouty found another area of exposed mesh on the anterior aspect of Ms. Bolyard's vagina. After discussion and informed consent<sup>17</sup>, Ms. Bolyard elected to return to the operating room with the hope of relieving her pain.<sup>18</sup> On August 19, 2013 Dr. Prouty returned Ms. Bolyard to the operating room again for a repeat excision of Avaulta mesh exposure. During the procedure Dr. Prouty described a "2mm x 12mm" area of "exposed graft at the distal superior cuff."<sup>19</sup> More importantly, Dr. Prouty described, "... there was an area at the right apex that was contracted a bit causing a tight band that was palpable within the vagina. Just using gentle pressure, I was able to stretch this band out of it. It was still present, however, it was much less significant."<sup>20</sup>

Unfortunately, Dr. Prouty's surgery was unsuccessful and Mr. Bolyard returned to his clinic on September 13, 2013 with the complaints of "...tenderness, tingling, throbbing and pain on intercourse."<sup>21</sup> On his exam Dr. Prouty found a recurrent grade 2 rectocele. He did not see any vaginal mesh exposure and elected to have Ms. Prouty observe the symptoms.

Currently, Ms. Bolyard is not sexually active secondary to severe, deep vaginal pain, which is different type of pain and in a different location than before surgery. The last attempt at sexual activity had to be stopped due to the severe pain which Ms. Bolyard scored as a 8 (of 10) on the Visual Analog Scale (VAS).

On October 4, 2014 in Nashville, Tennessee I personally examined Ms. Bolyard. The pertinent components of my examination demonstrated the following:

- Neurologic without gross deficit
- Abdomen without masses
- Vulva/Vagina/Urinary system:

Mild to moderate lichen sclerosis is present at the introitus and perineum. The vaginal epithelium is moderately atrophic. The urethra was in normal position and configuration without

<sup>14</sup> Deposition of Patricia Bolyard at 293-294; BOLYARDP\_FAGH\_MDR00276-277

<sup>15</sup> BOLYARDP\_FAGH\_MDR00276-277

<sup>16</sup> BOLYARDP\_WHWEC\_MDR00027

<sup>17</sup> BOLYARDP\_FAGH\_MDR00418-419

<sup>18</sup> Deposition of Patricia Bolyard at 307.

<sup>19</sup> BOLYARDP\_FAGH\_MDR00336

<sup>20</sup> BOLYARDP\_FAGH\_MDR00336-337

<sup>21</sup> BOLYARDP\_WHWEC\_MDR00002-4

any visible abnormality. Light palpation at the introitus incited diffuse, introital pain, which Ms. Bolyard states is consistent with her pain level from lichen sclerosis prior to surgery. On the VAS, Ms. Bolyard rated the pain at a 4-5 on the VAS. Deeper light palpation laterally along Levator ani muscles causes significant tenderness bilaterally. The intensity of the pain levels was equal on both sides. On the VAS, Ms. Bolyard rated the pain at a 6.

I was able to insert medium sized speculum (~2.5-3 cm wide) through the introitus without difficulty, however, due to exquisite tenderness deeper in the mid portion of the vagina caused Ms. Bolyard to visibly wince necessitating that I remove the speculum to relieve her pain. On the VAS, Ms. Bolyard rated the pain at a 6. The vaginal lumen length is within normal range. At the mid-portion of the vagina, just deep to the descending pubic rami was extremely painful to Ms. Bolyard (VAS = 7-8) with the left side being greater than the right side. Adduction of the thighs also elicited severe pain (VAS = 8). External palpation over the obturator foramen caused pain severe pain especially when the adductor muscle insertions were palpated. On the VAS, Ms. Bolyard rated the pain at an 8 with the left side being greater than the right. These findings are consistent with severe irritation in the region of the obturator foramen.

Palpation along the entire anterior vaginal wall and urethra was tender to light touch, again, causing Ms. Bolyard to noticeably wince. On the VAS, Ms. Bolyard rated the pain at a 6. Palpation along the entire posterior vaginal wall and urethra was nontender to palpation. On the VAS, Ms. Bolyard rated the pain at a 0. There was no visible/palpable evidence of mesh extrusion. The anterior, posterior and apical vaginal walls were well supported at rest and with Valsalva indicating there was no recurrence of pelvic organ prolapse.

Based upon my medical education, my review of the currently available medical literature pertaining to Ms. Bolyard, and my physical examination of Ms. Bolyard, with a high degree of medical certainty, I have come to the following medical diagnoses:

1. Pelvic Pain secondary to lichen sclerosis: lichen sclerosis is a very difficult condition to treat. She has had excellent care to date for this condition, yet it persists. This condition pre-dates the Avaulta mesh insertion and appears not to have been aggravated by the presences of the mesh.
2. Pelvic pain secondary to Avaulta mesh: Prognosis is poor. It is highly unlikely, even with aggressive physical therapy, biofeedback, or surgical resection for Ms. Bolyard to have complete resolution of the pelvic pain.
3. Pelvic Floor Myalgia: Prognosis is poor. It is highly unlikely, even with aggressive physical therapy, biofeedback and pelvic floor retraining, for Ms. Bolyard to have complete resolution of the pelvic floor dysfunction.
4. Urinary Urge Incontinence: With proper evaluation and surgical treatment it is possible for Ms. Bolyard to regain adequate control of her urine. However, repeat surgical

intervention will be more challenging and the likelihood of success will be less than first time surgery.

5. Dyspareunia secondary to lichen sclerosis: Continued treatment is advisable. Cure is unlikely.
6. Dyspareunia secondary to Avaulta mesh: Resolution of the deep vaginal pain is highly unlikely, even with aggressive surgery, physical therapy, biofeedback and pelvic floor retraining, for Ms. Bolyard to have complete resolution of her sexual dysfunction.
7. As a consequence, the lack of physical intimacy has already cost Ms. Bolyard a major component to her quality of life. Without a major reduction in her symptoms she is unlikely to ever regain the benefit of physical intimacy again in her life. The long-term impact on her quality of life is difficult to accurately ascertain, however, many studies have shown the long-term negative impact leading to feelings of isolation, loneliness, depression and suicide.
  - Sepulcri Rde et al: Depressive symptoms, anxiety, and quality of life in women with pelvic endometriosis. *Eur J Obstet Gynecol Reprod Biol.* 2009 Jan;142(1):53-6.
  - Mathias SD, Kupperman M et al: Chronic pelvic pain: prevalence, health-related quality of life, and economic correlates. *Obstet Gynecol.* 1996 Mar;87(3):321-7.

### **III. CASE SPECIFIC OPINIONS FOR PATRICIA BOLYARD**

My opinions are based on my personal knowledge, experience, and my investigation in this case. All of my opinions, and the basis of these opinions, are true and correct to the best of my knowledge and belief, including those related to scientific and medical issues, which I believe are true and correct to a reasonable degree of scientific and medical certainty. I do, however, reserve the right to supplement this report and my opinions in light of any additional material or information provided to me, including any reports submitted and/or any other discovery that is taken in this case. Furthermore, if called to testify, I would plan to use various demonstrative exhibits, animations, video recordings, and/or anatomic models to show the relevant anatomy and surgical procedures and to describe my opinions as set forth in this report. The materials I have reviewed and relied upon to form my opinions for this report are listed in Exhibit “C” to this report.

I have been asked to review the pertinent medical records (~3400 pages) pertaining to the care of Ms. Bolyard, to perform an independent medical exam of her and to provide this written report regarding my opinions of her care, surgery, and treatment. Also, I have been asked to provide a written diagnosis and prognosis, and have done the same in my report, attached hereto, following my review of her records and examination of Ms. Bolyard.

Determining the cause of a specific injury is a two step process. First, one must “rule in” potential causes. Second, through a process of elimination, “rule out” the least likely causes until



only the most likely causes remain under consideration. This process is known as differential diagnosing or differential etiology. It is a well-established and universally accepted methodology for determining the cause of injuries and illnesses by physicians throughout the United States. When determining the cause of a specific injury, it is necessary to “rule in” potential causes of the injury, and then by process of elimination, to “rule out” the least likely causes to arrive at the most likely cause. This process is known as differential diagnosis, or differential etiology, and it is a well-established and universally accepted methodology for determining the cause of injuries employed by physicians throughout the United States. I have used that methodology in arriving at my opinions in this case.

Based upon my review of Ms. Bolyard’s medical records, my experience and education, review of the available medical literature and examination of Ms. Bolyard, I currently hold the following opinions to a reasonable degree of medical certainty. I reserve the right to supplement and revise my opinions regarding Ms. Bolyard if further information becomes available.

1. Ms. Bolyard was not able to make a fully informed medical decision regarding the implantation of Avaulta mesh because Bard failed to fully disclose the risks, complications (both early and late) in Avaulta’s Instruction for Use.
2. Ms. Bolyard’s implanting surgeon was not able to provide the necessary and required information to Ms. Bolyard for an informed consent because Bard failed to fully reveal such information and failed to fully evaluate said information prior to launch.
3. Ms. Bolyard has developed complications as described above as a result of the Avaulta being implanted in her body.
4. As a result of these complications from the Avaulta device, Ms. Bolyard has suffered damages and will continue to suffer future damages.
5. I have personally reviewed Ms. Bolyard’s medical bills as a result of her treatment and surgeries related to the implantation of Avaulta device and its complications and I believe they are reasonable and necessary.
6. These complications have taken a significant impact on Ms. Bolyard’s quality of life. Prior to the surgery, she was healthy, physically and sexually active individual. Now Ms. Bolyard has been forced to dramatically reduce these activities due to her poorly controlled pelvic and vaginal pain. Ms. Bolyard can no longer enjoy a normal sexual life because of the severity of her vaginal and pelvic pain.



Ms. Bolyard suffered injuries as a direct result of the implantation of the Avaulta devices. As stated in my General Expert Liability Report, the polypropylene mesh utilized in the Avaulta product was not intended for human use. Bard did not convey this information to Ms. Bolyard.

Set out in my general causation expert report, several characteristics of the Marlex polypropylene mesh render it inherently unsafe for use in Ms. Bolyard. First, Bard utilizes non-medical grade polypropylene, the supplier of which has forbidden its use in humans because of its known degradation characteristics. Second, the mesh should have large pores at least 2 mm in its shortest diagonal. Third, it should be lightweight, i.e. less than less than 35 g/m<sup>2</sup> dense. Fourth, it should not be inserted blindly with metal trocars. Fifth, it should not have its flat mesh arms pulled through narrower, rounded trocar wounds. These characteristics, in my opinion to a reasonable degree of medical certainty and probability, caused Ms. Bolyard to suffer her permanent injuries: pelvic/vaginal pain, loss of enjoyment of hobbies such as playing volleyball,<sup>22</sup> and dyspareunia, and are a direct result of the C.R. Bard, Inc. products implanted into her body.

It is my opinion to a reasonable degree of medical certainty that Ms. Bolyard's post-implant medical treatment results from her complications stemming from the Bard implant. The medical records I have reviewed show that, following the implant, Ms. Bolyard experienced mesh extrusion, pain during intercourse, dysuria, chronic pelvic and vaginal pain, urinary leakage, severe infections, and dysuria. It is my opinion, to a reasonable degree of medical certainty and probability, that no other causes for her symptoms exists other than the mesh as she has not developed any medical conditions or life events that would cause her current problems.

Further, based on my background, education, training, and experience, it is my opinion that Dr. Prouty's treatment of Ms. Bolyard met the standard of care, when implanting and excising the mesh. It is also my opinion that the care and treatment by Dr. Prouty to remove mesh also met the standard of care. Both the implant and explant procedures were performed within the standard of care, with no evidence of surgeon error or deviation from the requisite procedural steps or the standard of care. Furthermore, none of the historical or medical conditions she had prior to 2010, would cause her current conditions.

As set forth in my general report, safer alternative designs to the mesh were available. And so, it is my opinion to a reasonable degree of medical certainty and probability that alternative treatments were available to treat Ms. Bolyard.

Also, as set out in my general report, C.R. Bard, Inc., failed to provide adequate warnings of the defects in the design of the mesh and system of implantation, as well as the adverse events resulting from those defects to Ms. Bolyard's physicians

Since Bard knew of these risks they should have been clearly placed on the IFU so that not only Ms. Bolyard implanting surgeon would be fully informed of the risks but also Ms. Bolyard could have been completely informed of the risk on her informed consent. The following lists the risks that were known but Ms. Bolyard was not informed of on her informed consent:

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<sup>22</sup> Deposition of Patricia Bolyard at 261.

1. Inadequate Pre-launch Testing and durability studies.
2. Ineffective procedure puts women through surgery with unacceptably high failure rate.
3. Dangerous Procedure with incomplete IFU specifications regarding tensioning and appropriate use of trocars thereby leading to complications and failure.
4. Inadequate data to support use of Avaulta in the Pelvic Floor.
5. That the Avaulta devices can cause chronic, permanent debilitating pain.
6. Incomplete warnings regarding increased inflammatory tissue response to Avaulta.
7. Incomplete warnings regarding the inherent nature of the Avaulta mesh a predictable increased immune response to the presence of the mesh is set off.
8. Incomplete warnings regarding the increased inflammatory and immune response causes increased risk for product breakdown and subsequent product failure.
9. Incomplete warning and pre-launch evaluations regarding the host's acute inflammatory response to Avaulta.
10. That Avaulta mesh can cause a lifelong risk of vaginal extrusion.
11. That Avaulta mesh can cause a lifelong risk of pelvic organ erosion.
12. That erosions and extrusions can be severe and incurable. Incomplete warning and pre-launch evaluations regarding the host's chronic inflammatory response to Avaulta.
13. Insufficient evaluation regarding implantation of Avaulta into the contaminated field of the vagina.
14. Insufficient evaluation regarding Avaulta product degradation/product Failure due to product degradation
15. Insufficient evaluation and warnings regarding Avaulta -related complications not seen in traditional repair.
16. That Bard knew of data that the risk of vaginal scarring was greater than it disclosed in its IFU.
17. Bard's Avaulta pelvic mesh products are defective due to Bard's failure adequately test the product prior to launch, failure to appropriately warn patients and health care providers of range, severity and magnitude of risks and complications including, but not limited to, the following:
  - a. The products' frequent tendencies to degrade, fragment, and elongate;

- b. The risk of the mesh causing a host versus implant immune response causing a chronic inflammation reaction resulting in pain and product failure;
- c. The risk of chronic infections resulting from the products;
- d. Risk of chronic foreign body reaction due to the presence of the product;
- e. The risk of permanent vaginal or pelvic scarring as a result of the products interaction with the host;
- f. The risk of permanent vaginal shorting as a result of the products;
- g. The risk of intractable pelvic, vaginal, urethral, and systemic pain and resulting from the products interaction with the body;
- h. The need for corrective or revision surgery to revise or attempt to remove the products;
- i. The severity of complications such as pelvic pain, vaginal pain, dyspareunia, overactive bladder, voiding pain that could arise as a result of implantation of the products;
- j. That Avaulta devices could cause permanent dyspareunia
- k. That Avaulta devices could cause permanent pelvic pain
- l. That the Avaulta device could cause narrowing of the vaginal vault.
- m. The frequency of complications that could arise as a result of implantation of the products;
- n. The pre-existing knowledge of the severity and frequency of complications resulting from the products implantation;
- o. Folding of the product inside the body;
- p. Treatment of pelvic organ prolapse and stress urinary incontinence with the products is no more effective than feasible available alternatives;
- q. Treatment of pelvic organ prolapse and stress urinary incontinence with the products exposes patients to greater risk than feasible available alternatives;
- r. Treatment of pelvic organ prolapse and stress urinary incontinence with the products makes future surgical repair more difficult than feasible available alternatives;

- s. The use of the products puts the patients at greater risk of requiring additional surgery;
  - t. The removal of the products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life;
  - u. Complete removal of the products is most likely not possible and may not result in resolution of the complications, including pain; and recurrent urinary leakage and pelvic organ prolapse.
18. Insufficient evaluation regarding and warning regarding the pullout forces of the Avaulta.
19. Insufficient evaluation regarding and warning regarding the pullout forces of Avaulta if the mesh were to be adjusted (pulled back and forth) during the mesh tensioning portion of the procedure.
20. Insufficient evaluation regarding and warning regarding the mesh sling anchoring configuration and "rolling potential" once in place in the body and rectus abdominis muscle and fascia.
21. Insufficient evaluation regarding, warning and IFU guidance for Avaulta placement in morbidly obese patients.

Ms. Bolyard did not receive information about the above risks because Bard did not disclose them fully in its IFU and surgeons, including the implanting surgeon in Ms. Bolyard's case, were not made aware of them. This is true despite information readily available to Bard about these risks, which predate the launch of the device. Because of this, Ms. Bolyard's implanting surgeon could not pass this information on to her and properly warn her about the risks associated with the Avaulta device. Ms. Bolyard was unable to make a fully informed decision about having the Bard device implanted. As a result, to a reasonable degree of medical certainty, Ms. Bolyard suffered injuries that were not disclosed to her by Bard and the inadequate disclosure of these risks were a substantial factor and/or cause of Ms. Bolyard's injuries.

I reserve the right to amend and/or supplement this report if new discovery or facts necessitate amendment or supplementation.

Dated this 8th day of October, 2014.



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Daniel S. Elliott

# **EXHIBIT A**

## Curriculum Vitae and Bibliography

### Daniel S. Elliott, MD

#### Present Academic Rank and Position

<b>Consultant</b> - Department of Urology, Mayo Clinic, Rochester, Minnesota	07/2003 - Present
<b>Associate Professor of Urology</b> - Mayo Clinic College of Medicine	01/2013 - Present

#### Education

Biola University - BS, Biological Science	1988
School of Medicine, Loma Linda University - MD	1993
Mayo School of Graduate Medical Education, Mayo Clinic College of Medicine - Internship, General Surgery	1993 - 1994
Mayo School of Graduate Medical Education, Mayo Clinic College of Medicine - Resident, Urologic Surgery	1994 - 1999
Baylor College of Medicine - Fellow, Neurourology, Urodynamics and Voiding Dysfunction	1999 - 2000

#### Additional Education

UCLA State-of-the-Art Urology UCLA Marina del Rey, California	03/2004
UCLA State-of-the-Art Urology UCLA Marina del Rey, California	03/2005
UCLA State-of-the-Art Urology UCLA Marina del Rey, California	03/2006
UCLA State-of-the-Art Urology UCLA Marina del Rey, California	03/2007
UCLA State-of-the-Art Urology UCLA Marina del Rey, California	03/2008
UCLA State-of-the-Art Urology UCLA Marina del Rey, California	03/2009
Coloplast Surgical Training - Male Sling New York, New York	06/2009
UCLA State-of-the-Art Urology UCLA Marina del Rey, California	03/2010
UCLA State-of-the-Art Urology UCLA Marina del Rey, California	03/2011

UCLA State-of-the-Art Urology UCLA Marina del Rey, California	03/2012
Comprehensive Review Course in Female Pelvic Medicine and Reconstructive Surgery Dallas, Texas	04/2013
AUA Hands-On Ultrasound Training Course Rochester, Minnesota	10/2014

**Certifications****Board Certifications****American Board of Urology**

Urology	2002 - Present
Urology/Female Pelvic Medicine and Reconstructive Surgery	08/2013 - Present

**Honors/Awards**

<b>AUA Resident Award</b> - John D. Silbar North Central Section	10/1998
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<b>Urology Grant Recipient</b> - Pfizer Scholars	01/1999
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<b>DeWeerd Travel Award Recipient</b>	06/1999
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<b>Annual Audio-Visual Award - AUA</b> - American Urological Association, Washington, District of Columbia	05/2011
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Small intestinal submucosa urethral wrap as a salvage treatment option following multiple failed artificial urinary sphincters - Third Prize - Landon Trost, Daniel Elliott

<b>Best Reviewer in 2011 Award - Urodynamics/Incontinence/Female Urology/Neurourology</b> - The Journal of Urology	05/2012
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<b>Best Reviewer in 2012 Award - Urodynamics/Incontinence/Female Urology/Neurourology</b> - The Journal of Urology	05/2013
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<b>Annual Audio-Visual Award - AUA</b> - American Urological Association, San Diego, California	05/2013
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Long-Term Outcomes of Patients Undergoing the Standard Versus Modified (5 Points of Fixation, 1 Point of Plication) Technique for Virtue Male Sling Placement - First Honorable Mention - Landon Trost, Daniel Elliott

**Previous Professional Positions and Major Appointments**

<b>Senior Associate Consultant</b> - Department of Urology, Mayo Clinic, Rochester, Minnesota	07/2000 - 06/2003
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<b>Assistant Professor of Urology</b> - Mayo Clinic College of Medicine	04/2002 - 12/2012
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**Professional & Community Memberships, Societies and Services****Professional Memberships & Services**

American Medical Association	
Member	1991 - 2001
American Association of Clinical Urologists	
Member	1998 - 2005
American Urological Association	
Member	2000 - Present
International Continence Society	



Member	2001 - Present
Society for Urodynamics & Female Urology	
Member	2002 - Present
Education Committee	
Committee Member	08/2014 - Present
Minnesota Medical Association	
Member	2002 - Present
Zumbro Valley Medical Society	
Member	2002 - Present
Olmsted County Medical Association	
Member	2002 - Present
International Urogynecologic Society	
Member	2003 - Present
Society of Urologic Prosthetic Surgeons	
Member	2005 - Present
Society of Laparoendoscopic Surgeons	
Member	2005 - Present
Minimally Invasive Robotic Association	
Member	2005 - Present
Minnesota Urological Society	
Member	2006 - Present
European Association of Urology	
International Member	03/2013 - Present
Section of Genitourinary Reconstructive Surgeons	
International Member	03/2013 - Present
Committee Member	04/2014 - Present
Section of Female and Functional Urology	
International Member	04/2013 - Present
International Urogynecologic Association	
Member	05/2013 - Present
International Pelvic Pain Society	
Member	05/2014 - Present

## **Journal Responsibilities**

### **Journal Editorial Responsibilities**

Journal of Robotic Surgery

Consulting Editor

Journal of Gynecology and Obstetrics

Editorial Board Member

### **Journal Other Responsibilities**

Mayo Clinic Proceedings

Reviewer

Neurourology and Urodynamics

Reviewer  
The Journal of Urology  
Reviewer  
Journal of Investigative Urology  
Reviewer  
Nature Clinical Practice Urology  
Reviewer  
Mayo Clinic Health Letter  
Reviewer  
Archives of Gynecology and Obstetrics  
Reviewer  
Journal of Endourology  
Reviewer  
European Journal of Obstetrics & Gynecology and Reproductive Biology  
Reviewer  
Cleveland Clinic Journal of Medicine  
Reviewer  
Contemporary Clinical Trials  
Reviewer  
International Urogynecology Journal  
Reviewer  
Canadian Urological Association Journal  
Reviewer, Canada  
Urologia Internationalis  
Reviewer

## **Educational Activities**

### **Teaching Intramural**

Prostate Pathology 03/2005  
Mayo Medical School  
Rochester, Minnesota

## **Institutional/Departmental Administrative Responsibilities, Committee**

### **Memberships and Other Activities**

#### **Mayo Clinic in Rochester**

Department of Urology  
Education Committee  
Committee Member 02/2003 - 11/2008  
Committee Member 10/2013 - Present

## **Presentations Extramural**

### **National/International**

#### **Invited**

Robotic Urogynecologic Surgery 3rd Annual World Robotic Urology Symposium Orlando, Florida	03/2008
Robotic Sacrocolpopexy 2009 International Robotic Urology Symposium (IRUS), Henry Ford Health System Las Vegas, Nevada	01/2009
Current Status Robotic GYN Surgery 2010 International Robotic Urology Symposium (IRUS), Henry Ford Health System Las Vegas, Nevada	01/2010
Robotic Sacrocolpopexy 28th World Congress on Endourology and SWL Chicago, Illinois	09/2010
Female Urology 28th World Congress on Endourology and SWL Chicago, Illinois	09/2010
Optimizing Quality of Life With Regard to Urologic Function After Sacrectomy The 4th Annual Sacral Tumor Study Group Conference, Massachusetts General Hospital Boston, Massachusetts	01/2013
Treatment of Bladder and Urethral Mesh Erosion: Remove and Reconstruct Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) Scottsdale, Arizona	02/2015

**Oral**

Long Term Follow-Up of Endoscopically Treated Upper Tract Transitional Cell Carcinoma American Urological Association Annual Meeting Las Vegas, Nevada	04/1995
Transabdominal Enzymatic Ablation of the Prostate in the Canine Model: Evaluation for Use for the Treatment of Outflow Obstruction Due to Benign Prostatic Hyperplasia Urodynamics Subsection Meeting, American Urological Association Orlando, Florida	05/1996
Long Term Analysis of 323 AMS 800 Artificial Urinary Sphincters Urodynamics Subsection Meeting, American Urological Association Orlando, Florida	05/1996
Analysis of Functional Durability of AMS 800 Artificial Urinary Sphincter: The Mayo Clinic Results American Urological Association Annual Meeting New Orleans, Louisiana	04/1997
Long Term Follow-Up Primary Realignment of Urethral Disruption Following Pelvic Fracture American Urological Association Annual Meeting New Orleans, Louisiana	04/1997

Does Reoperation on an Artificial Urinary Sphincter Increase the Likelihood for Further Reoperations for Mechanical or Nonmechanical Failure? American Urological Association Annual Meeting San Diego, California	06/1998
Is Nephroureterectomy Necessary in All Cases of Upper Tract Transitional Cell Carcinoma? Long Term Results of Conservative Endourology Management of Upper Tract Transitional Cell Carcinoma in Individuals with Normal Contralateral Kidneys American Urological Association Annual Meeting Dallas, Texas	05/1999
Durability of Cadaveric Pubovaginal Sling American Urological Association Annual Meeting Anaheim, California	06/2001
Does the Addition of Antibiotic Prophylaxis to CIC Alter the Incidence of UTI? American Urological Association Annual Meeting Orlando, Florida	06/2002
Surgical Approach for Placement of SPARC Suburethral Sling North Central Section, American Urological Association Chicago, Illinois	10/2002
SPARC suburethral sling: technique and results (Video Presentation) Western Section, American Urological Association Kauai, Hawaii	11/2002
Robotic laparoscopic sacrocolpopexy: new surgical technique for the treatment of vaginal vault prolapse (Video Presentation) American Urological Association Chicago, Illinois	04/2003
Colloquium-ICS/IUGA 2004 Paris, France	08/2004
Robotic-Assisted Laparoscopic Management of Vaginal Vault Prolapse Minimally Invasive Robotics Association Innsbruck, Austria	12/2005
Advancement in Salvage Procedure Following Failed Artificial Urinary Sphincter: Tandem Transcorporal Artificial Urinary Sphincter Cuff Technique (Video Presentation) American Urological Association Atlanta, Georgia	05/2006
Tandem Transcorporal Artificial Urinary Sphincter Cuff Salvage Technique Following Previous Cuff Erosion and Infection: Surgical Description and Outcome Western Section, American Urological Association Maui, Hawaii	10/2006
Assessment of Durability of Robotic Sacrocolpopexy for the Treatment of Vaginal Vault Prolapse Minimally Invasive Robotics Association New York, New York	01/2007
Minimally Invasive Advances: Stress Incontinence Mayo Clinic Rochester, Department of Urology Kohala Coast, Hawaii	02/2007

Treatment Options for the Failed Sling Mayo Clinic Rochester, Department of Urology Kohala Coast, Hawaii	02/2007
American Urological Association Annual Meeting Anaheim, California	05/2007
Robotics use in Gynecology: the Mayo Clinic experience Robotic Surgery: Facts or Fiction? Milano, Italy	06/2007
Indication and Management of Artificial Urinary Sphincter 7th Osijek Urological Days Osijek, Croatia	10/2007
Robotics Use in Gynecology 7th Osijek Urological Days Osijek, Croatia	10/2007
Robotic Urogynecologic Surgery 3rd Annual World Robotic Urology Symposium Orlando, Florida	03/2008
Latest Advances and Treatment of Complications in Minimally Invasive Treatments for Stress Incontinence American Urological Association (AUA) Orlando, Florida	05/2008
Severe, recurrent bladder neck contracture after prostatectomy: Salvage with urethral wall stent (Video and Poster Presentation) American Urological Association (AUA) Orlando, Florida	05/2008
Surgical Advances of Stress Urinary Incontinence Indian American Urological Association (IAUA) Orlando, Florida	05/2008
Robotic Sacrocolpopexy International Robotic Urology Symposium, Henry Ford Health System Las Vegas, Nevada	01/2009
Overactive Bladder: Current Concepts of Management Mayo Clinic, Department of Urology, Rochester Meeting Kona, Hawaii	02/2009
Minimally Invasive Advances: Stress Incontinence Mayo Clinic, Department of Urology, Rochester Meeting Kona, Hawaii	02/2009
Management of Complications Following Anti-Incontinence Procedures Mayo Clinic, Department of Urology, Rochester Meeting Kona, Hawaii	02/2009
American Urological Association (AUA) Chicago, Illinois	04/2009
Robotic repair for vaginal prolapse has significant benefits North Central Section of the AUA - 83rd Annual Meeting Scottsdale, Arizona	11/2009

Current Status Robotic GYN Surgery International Robotic Urology Symposium, Henry Ford Health System Las Vegas, Nevada	01/2010
Robotics for Female Pelvic Reconstruction: Who, When and What? American Urological Association (AUA) San Francisco, California	05/2010
Results of Urethral Wrap As Salvage Treatment Option Following Multiple Failed Artificial Urinary Sphincters North Central Section of the AUA Chicago, Illinois	09/2010
Small intestinal submucosa urethral wrap as a salvage treatment option following multiple failed artificial urinary sphincters Audio-Visual American Urological Association (AUA) Washington, District of Columbia	05/2011
Long-Term Results of Small Intestinal Submucosa at Artificial Urinary Sphincter Placement for Management of Persistent / Recurrent Incontinence Following Multiple Sphincter Failures and Erosions North Central Section of the AUA Rancho Mirage, California	10/2011
OAB Current Concepts and Management Mayo Clinic Reviews in Urology Kohala Coast, Hawaii	02/2012
Treatment and Evaluation of the Complicated Artificial Urinary Sphincter Patient Mayo Clinic Reviews in Urology Kohala Coast, Hawaii	02/2012
Transvaginal Mesh Kits Complications and Alternatives Mayo Clinic Reviews in Urology Kohala Coast, Hawaii	02/2012
Vaginal Mesh for POP: what's the data show? American Urological Association (AUA) Atlanta, Georgia	05/2012
How do different centres perform Robot-assisted-Sacrocolpopexy? 4th Annual Society of European Robotic Gynecological Surgery (SERGS) Marseille, France	06/2012
Comparative Surgical Complications of the Robotic Sacrocolpopexy for Pelvic Organ Prolapse vs. Traditional Transabdominal Sacrocolpopexy European Robotic Urology Symposium (ERUS) London, United Kingdom	09/2012
Effect of prior radiotherapy and ablative therapy on surgical outcomes for the treatment of rectourethral fistulas Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Las Vegas, Nevada	02/2013

Robotic Transvesical Rectourethral Fistula Repair Following a Robotic Radical Prostatectomy (Video Presentation) Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Las Vegas, Nevada	02/2013
Impact of Patient Obesity on Robotic Sacrocolpopexy for the Treatment of Vaginal Vault Prolapse Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Las Vegas, Nevada	02/2013
Long-Term Outcomes of Patients Undergoing the Standard Versus Modified (5 Points of Fixation, 1 Point of Plication) Technique for Virtue Male Sling Placement (Video Presentation) American Urological Association (AUA) San Diego, California	05/2013
Robotic Transvesical Rectourethral Fistula Repair Following a Robotic Radical Prostatectomy (Video Presentation) American Urological Association (AUA) San Diego, California	05/2013
Effect of prior radiotherapy and ablative therapy on surgical outcomes for the treatment of rectourethral fistulas American Urological Association (AUA) San Diego, California	05/2013
The Impact of InhibiZone on Artificial Urinary Sphincter Infection Rate American Urological Association (AUA) San Diego, California	05/2013
Impact of Patient Obesity on Robotic Sacrocolpopexy for the Treatment of Vaginal Vault Prolapse American Urological Association (AUA) San Diego, California	05/2013
Long Term Risk for Repeat Anti-Incontinence Surgery following Urethrolisis: A Review of 100 Patients American Urological Association (AUA) San Diego, California	05/2013
Impact of patient obesity on robotic sacrocolpopexy for the treatment of vaginal vault prolapse 3rd International Meeting "Challenges in Endourology & Functional Urology" Paris, France	06/2013
Long-Term Outcomes for Artificial Urinary Sphincter Reimplantation Following Prior Device Explantation for Erosion and/or Infection South Central Section of the AUA Chicago, Illinois	09/2013
Effect of prior radiotherapy and ablative therapy on surgical outcomes for the treatment of rectourethral fistulas 2nd Joint Section Meeting of ESFFU, ESGURS, and ESOU Tübingen, Germany	10/2013



Long-term impact of artificial urinary sphincter reimplantation following prior device explantation for erosion and/or infection 2nd Joint Section Meeting of ESFFU, ESGURS, and ESOU Tübingen, Germany	10/2013
Impact of patient obesity on robotic sacrocolpopexy for the treatment of vaginal vault prolapse 2nd Joint Section Meeting of ESFFU, ESGURS, and ESOU Tübingen, Germany	10/2013
Long-Term Device Outcomes for Artificial Urinary Sphincter Reimplantation Following Prior Explantation for Erosion or Infection Society of Urodynamics Female Pelvic Medicine & Urogenital Reconstruction Miami, Florida	02/2014
Risk Factors for Intraoperative Conversion During Robotic Sacrocolpopexy Society of Urodynamics Female Pelvic Medicine & Urogenital Reconstruction Miami, Florida	02/2014
Results of artificial urinary sphincter reimplantation following previous erosion and/or infection 29th Annual Congress of the European Association of Urology Stockholm, Sweden	04/2014
Autologous Transobturator Mid-Urethral Sling Placement: A Novel Outpatient Procedure for Female Stress Urinary Incontinence (Video Presentation) American Urological Association (AUA) Orlando, Florida	05/2014
Surgical Management of Female Benign Urethral Stricture Disease: A Ten Year Experience American Urological Association (AUA) Orlando, Florida	05/2014
Urethral Management at the Time of Artificial Urinary Sphincter Erosion, Is Urethral Catheterization Alone Enough? North Central Section of the American Urological Association (AUA) Chicago, Illinois	09/2014
Autologous Transobturator Mid-Urethral Sling Placement for Female Stress Urinary Incontinence (Video Presentation) North Central Section of the American Urological Association (AUA) Chicago, Illinois	09/2014
<b>Poster</b>	
Robot-Assisted Laparoscopic Sacrocolpopexy for Treatment of High Grade Vaginal Vault Prolapse: Surgical Technique and Initial Experience 29th Congress of the Societe Internationale d'Urologie Paris, France	09/2007
Robot Sacrocolpopexy: A Review of the Learning Curve in Fifty Cases 4th World Congress on Controversies in Urology (CURy) Paris, France	01/2011
Impact of Radiotherapy on Surgical Repair and Outcomes in Patients with Rectourethral Fistula. 67th Annual Meeting of the Canadian Urological Association Alberta, Canada	06/2012

Term Device Outcomes for Artificial Urinary Sphincter Reimplantation Following 05/2014  
 Prior Explantation for Erosion or Infection  
 American Urological Association (AUA)  
 Orlando, Florida

Factors Associated with Intraoperative Conversion During Robotic 09/2014  
 Sacrocolpopexy  
 North Central Section of the American Urological Association (AUA)  
 Chicago, Illinois

## **Regional**

### **Invited**

Rectocele 10/2004  
 Office of Women's Health brown bag  
 Rochester, Minnesota

Incontinence and Other Urological Issues 08/2007  
 Radio Broadcast, Hosted by Dr. Thomas Shives  
 HealthLine - KROC Radio  
 Rochester, Minnesota

A Practical Approach to Treating Incontinence 10/2008  
 Clinical Reviews, Rochester Civic Center  
 Rochester, Minnesota

A Practical Approach to Treating Incontinence 11/2008  
 Clinical Reviews, Rochester Civic Center  
 Rochester, Minnesota

Incontinence and Other Urological Issues 03/2010  
 Radio Broadcast, Hosted by Dr. Thomas Shives  
 Medical Edge Weekend - KROC Radio  
 Rochester, Minnesota

Urinary Incontinence 03/2011  
 Radio Broadcast, Hosted by Dr. Thomas Shives  
 Medical Edge Weekend - KROC Radio  
 Rochester, Minnesota

Incontinence: Causes and Treatments 02/2013  
 Prostate Cancer Support Group  
 Rochester, Minnesota

Urinary Incontinence 05/2014  
 Radio Broadcast, Hosted by Dr. Thomas Shives  
 Medical Edge Weekend - KROC Radio  
 Rochester, Minnesota

### **Oral**

Paratesticular Angiomyofibroblastoma 09/1995  
 North Central Section, American Urological Association  
 Minneapolis, Minnesota

Does the Degree of Preoperative Elevation PSA Exclude a Patient for 10/1996  
 Consideration for Radical Retropubic Prostatectomy?  
 North Central Section, American Urological Association  
 Tucson, Arizona

Does Reoperation of an Artificial Sphincter Place the Patient at an Increased Risk for Subsequent Reoperation 10/1998  
 North Central Section, American Urological Association  
 Amelia Island, Florida

Is Fascia Lata Allograft Material Trustworthy for Pubovaginal Sling Repair 10/2000  
 North Central Section, American Urological Association  
 Phoenix, Arizona

Combined Stent and Artificial Urinary Sphincter for Management of Severe Recurrent Bladder Neck Contractures and Stress Incontinence after Prostatectomy: A Long-Term Evaluation. 10/2000  
 North Central Section, American Urological Association  
 Phoenix, Arizona

Does Nocturnal Deactivation of the Artificial Urinary Sphincter Lessen the Risk for Urethral Atrophy? 10/2000  
 North Central Section, American Urological Association  
 Phoenix, Arizona

Robotics Surgery for Vaginal Prolapse 06/2007  
 Controversies in Women's Health Symposium 2007  
 Nisswa, Minnesota

## Research Grants Awarded

### Completed Grants

#### Federal

Co-Investigator Selenium and Vitamin E Cancer Prevention Trial (SELECT). 01/2010 - 12/2010  
 Funded by National Cancer Institute. (U10 CA 37429-SELECT)

#### Industry

Principal Investigator Are There Histological and Tensile Strength Variations in Autologous, Allograft and SIS Pubovaginal Slings Over Time Using the Rabbit Model. Funded by Mentor Corporation. 10/2002 - 09/2003  
 (MENTOR #5, 1A4575)

Co-Investigator Single Looped Mechanical Urinary Sphincter: Determination of Required Urethral Constriction Forces to Provide Adequate Urinary Continence in the Canine Model. Funded by Dacomed, Inc. (Dacomed #1) 10/1995 - 12/1995

Co-Investigator Clinical Investigation of the Safety and Performance of Timm Medical Technologies' Artificial Urinary Sphincter (TIMM-AUS). 06/1999 - 02/2005  
 Funded by Timm Medical Technologies. (Timm # 1)

Co-Investigator A Randomized, Double-Blind, Parallel-Group Study to Investigate the Effects of a Single Oral Dose of L-753099 Compared to Placebo and Tolerodine on Urodynamic Parameters in Healthy Male Volunteers. Funded by Merck & Co., Inc. (Merck 138) 07/1999 - 12/2003

Co-Investigator The Safety, Local Tolerability, Pharmacokinetics, and Risk Benefit of Oxybutynin Transvaginal Rings (TVR) in Women with a History of Overactive Bladder. Funded by Advanced Biologics. 01/2001 - 12/2003  
 (BIOLOGICS #1)

Co-Investigator An Eight-Week, Double-Blind, Randomized, Parallel Group Design, Multicenter Study of FLOMAX Capsules, 0.4 mg Daily Vs. Placebo, in Female Patients w/ Lower Urinary Tract Symptoms (LUTS) w/ a Significant Component of Voiding Symptoms. Funded by Boehringer Ingelheim. (BOEHRINGER #34) 06/2001 - 07/2003

Co-Investigator Veritas Collagen Matrix Urological Sling Postmarketing Clinical Study Protocol. Funded by Bio-Vascular, Inc. (BIOVASCULAR #1) 10/2001 - 09/2003

**Mayo Clinic**

Principal Investigator Transurethral Enzymatic Ablation of the Prostate (TEAP); Short-term Concentration Study. Funded by Department Discretionary Funds. (Immuno 2) 09/1995 - 12/2003

## Bibliography

### Peer-reviewed Articles

1. Gleason PE, **Elliott DS**, Zimmerman D, Smithson WA, Kramer SA. Metastatic testicular choriocarcinoma and secondary hyperthyroidism: case report and review of the literature. *J Urol*. 1994 Apr; 151(4):1063-4. PMID:8126794.
2. **Elliott DS**, Blute ML, Patterson DE, Bergstralh EJ, Segura JW. Long-term follow-up of endoscopically treated upper urinary tract transitional cell carcinoma. *Urology*. 1996 Jun; 47(6):819-25. PMID:8677570. DOI:10.1016/S0090-4295(96)00043-X.
3. **Elliott DS**, Barrett DM. Long-term followup and evaluation of primary realignment of posterior urethral disruptions. *J Urol*. 1997 Mar; 157(3):814-6. PMID:9072573.
4. **Elliott DS**, Barrett DM. The artificial urinary sphincter in the female: indications for use, surgical approach and results. *Int Urogynecol J Pelvic Floor Dysfunct*. 1998; 9(6):409-15. PMID:9891964.
5. **Elliott DS**, Barrett DM. Mayo Clinic long-term analysis of the functional durability of the AMS 800 artificial urinary sphincter: a review of 323 cases. *J Urol*. 1998 Apr; 159(4):1206-8. PMID:9507835.
6. Brown JA, **Elliott DS**, Barrett DM. Postprostatectomy urinary incontinence: a comparison of the cost of conservative versus surgical management. *Urology*. 1998 May; 51(5):715-20. PMID:9610584.
7. **Elliott DS**, Barrett DM. The artificial genitourinary sphincter. *Digital Urology Journal*. 1998 Jul.
8. **Elliott DS**, Timm GW, Barrett DM. An implantable mechanical urinary sphincter: a new nonhydraulic design concept. *Urology*. 1998 Dec; 52(6):1151-4. PMID:9836575.
9. **Elliott DS**, Boone TB. Urethral devices for managing stress urinary incontinence. *Journal of Endourology*. 2000 Feb; 14(1):79-83. PMID:10735576.
10. **Elliott DS**, Barrett DM. Artificial urinary sphincter implantation using a bulbous urethral cuff: perioperative care. *Urol Nurs*. 2000 Apr; 20(2):89-90, 95-8. PMID:11998129.
11. Frank I, **Elliott DS**, Barrett DM. Success of de novo reimplantation of the artificial genitourinary sphincter. *J Urol*. 2000 Jun; 163(6):1702-3. PMID:10799164.
12. Petrou SP, **Elliott DS**, Barrett DM. Artificial urethral sphincter for incontinence. *Urology*. 2000 Sep 1; 56(3):353-9. PMID:10962293.
13. **Elliott DS**, Boone TB. Is fascia lata allograft material trustworthy for pubovaginal sling repair? *Urology*. 2000 Nov 1; 56(5):772-6. PMID:11068297.
14. **Elliott DS**, Boone TB. Recent advances in the management of the neurogenic bladder. *Urology*. 2000 Dec 4; 56(6 Suppl 1):76-81. PMID:11114567.
15. **Elliott DS**, Boone TB. Combined stent and artificial urinary sphincter for management of severe recurrent bladder neck contracture and stress incontinence after prostatectomy: a long-term evaluation. *J Urol*. 2001 Feb; 165(2):413-5. PMID:11176385. DOI:10.1097/00005392-200102000-00014.
16. **Elliott DS**, Mutchnik S, Boone TB. The "bends" and neurogenic bladder dysfunction. *Urology*. 2001 Feb; 57(2):365. PMID:11182361.

17. Kim IY, **Elliott DS**, Husmann DA, Boone TB. An unusual presenting symptom of sarcoidosis: neurogenic bladder dysfunction. *J Urol*. 2001 Mar; 165(3):903-4. PMID:11176503.
18. Petrou SP, **Elliott DS**. Artificial urethral sphincter for incontinence in adults. *Drugs Today (Barc)* 2001 Apr; 37(4):237-244. PMID:12768224.
19. **Elliott DS**, Barrett DM, Gohma M, Boone TB. Does nocturnal deactivation of the artificial urinary sphincter lessen the risk of urethral atrophy? *Urology*. 2001 Jun; 57(6):1051-4. PMID:11377302.
20. **Elliott DS**, Segura JW, Lightner D, Patterson DE, Blute ML. Is nephroureterectomy necessary in all cases of upper tract transitional cell carcinoma? Long-term results of conservative endourologic management of upper tract transitional cell carcinoma in individuals with a normal contralateral kidney. *Urology*. 2001 Aug; 58(2):174-8. PMID:11489692.
21. Lightner DJ, **Elliott D**, Gillett M. Surgeon's corner. Transvaginal culdoplasty for posthysterectomy vaginal vault prolapse. *Contemp Urol*. 2003 Sep; 15(9):15-22.
22. DiMarco DS, **Elliott DS**. Tandem cuff artificial urinary sphincter as a salvage procedure following failed primary sphincter placement for the treatment of post-prostatectomy incontinence. *J Urol*. 2003 Oct; 170(4 Part 1):1252-4. PMID:14501735.
23. **Elliott DS**, Barrett DM. Current indications for the use of the artificial genitourinary sphincter and management of its complications. *The Scientific World Journal*. 2004; 4(S1):114-27.
24. Di Marco DS, Chow GK, Gettman MT, **Elliott DS**. Robotic-assisted laparoscopic sacrocolpopexy for treatment of vaginal vault prolapse. *Urology*. 2004 Feb; 63(2):373-6. PMID:14972496. DOI:10.1016/j.urology.2003.09.033.
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45. Trost L, **Elliott D** . Small intestinal submucosa urethral wrap at the time of artificial urinary sphincter placement as a salvage treatment option for patients with persistent/recurrent



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